

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

UNITED STATES OF AMERICA

v.

DAVID BURKE,

a/k/a, "David Johnson,"

Defendant.

Criminal Nos. 1:14-cr-397-3

Hon. Anthony J. Trenga

Sentencing Date: September 17, 2015

**POSITION OF THE UNITED STATES
WITH RESPECT TO SENTENCING**

For over three years, David Burke was the Director of Sales for SB Medical, Inc. and its affiliate, TC Medical Group. Burke preached dishonesty as he instructed his staff on how to conceal the foreign and illegal nature of the products they were selling. If a staff-member encountered a potential client who insisted SB Medical's products were illegal, Burke took the phone and gathered his employees so they could all appreciate and emulate his deceitful tactics. According to one witness, Burke even went so far as to fire a sales representative because he "didn't know how to lie."

Mr. Burke is by far the most culpable defendant that has pled guilty in this case. Without Burke's leadership, it is inconceivable that SB Medical could have distributed over \$30 million worth of misbranded pharmaceuticals. And that is not just the Government's assessment; it is Burke's as well. Just before his arrest, Burke sent a text message to CEO Tzvi Lexier, insisting that he (Burke) was the "MOST instrumental part of this company from day f - -king one." "No one will ever

be able to do what I did for you,” he continued. “It isn’t just the cosmetics ... it’s the infrastructure,” “[t]he FDA agents that had their attention drawn elsewhere,” and “the clients that would have left had I not got involved” and did “what it took to make sure [money] stayed in all our pockets.” PSR ¶ 31(s).

The presentence report correctly calculated the defendant’s Total Offense Level as 31, his Criminal History Category as I, and the resulting advisory Guidelines Range as **108 to 135 months’ imprisonment**. The Government submits that a Guidelines sentence is appropriate because Burke helped lead a sophisticated and massive criminal organization and knowingly endangered tens of thousands of American patients. Additionally, the United States respectfully requests that the Court order forfeiture in the agreed-upon amount of \$1,301,616, which reflects the salary and commissions that the defendant received from SB and TC Medical.

I. Offense of Conviction

From 2011 until his arrest on December 23, 2014, Mr. Burke exercised control over nearly every aspect of SB Medical’s illegal business. Not only was Burke the company’s most prolific salesmen and its Director of Sales, he also tracked and coordinated shipments from overseas and provided detailed instructions to U.S.-based drop-shippers. Burke frequently told drop-shippers to ignore safety regulations mandating that certain pharmaceuticals (so-called “cold-chained” products) be kept cold. For instance, Burke once chastised Rivka Rabi for attempting to keep cold-chained products cold, asserting that: “You do not need to

put ice in anything going forward.” Meanwhile, Burke promised clients that “Frozen products such as Botox are shipped overnight Priority Fed Ex (medical/frozen special handling) on several kilograms of dry ice ... All products are transported and stored in climate controlled environments.” PSR ¶ 31(f). Burke also instructed overseas suppliers on how to smuggle illegal pharmaceuticals past U.S. customs by such means as false customs declarations and breaking large shipments down into smaller ones. PSR ¶ 31(l)(m).

Burke understood that the company’s actions were illegal and could land him in an American prison. He once advised a co-conspirator that “importing ‘medical devices’ for sale is against the law,” so “you should make as much as you can while you can.” PSR ¶ 31(e). “I go with the thought of every day is my last and make the best of it,” Burke added. *Id.* Burke provided different advice to underlings when it suited his purposes, however, such as when he assured Rivka Rabi that an FDA warning letter sent to her house “really isn’t a big issue at all.” PSR ¶ 31(r).

Burke would do anything to “make sure [money] stayed in all our pockets.” PSR ¶ 31(s). This apparently included selling misbranded drugs to cancer patients. In January 2014, Burke led the company’s efforts to expand to cancer drugs, once emailing several co-conspirators under the subject line “Oncology Products” and directing them to “let me know what [oncology] products we can get our hands on.” PSR ¶ 31(p). “English packaging will be an easier and safer sale,” he added. *Id.*

Burke's importance to the company was reflected in the over \$1.3 million he received in salary and commissions. PSR ¶ 29. It was also reflected in his guilty plea to the following five felonies:

Charge	Statute	Maximum Penalties
Conspiracy	18 U.S.C. § 371	5 years' imprisonment; a fine of \$250,000; a \$100 special assessment; and three years' supervised release.
Smuggling	18 U.S.C. § 545	20 years' imprisonment; a fine of \$250,000; a \$100 special assessment; and three years' supervised release.
Introducing Misbranded Drugs and Devices into Interstate Commerce	21 U.S.C. § 331(a)	3 years' imprisonment; a fine of \$10,000; a \$100 special assessment; and one year supervised release.
Unlicensed Wholesale Distribution of Prescription Drugs	21 U.S.C. § 331(t)	10 years' imprisonment; a fine of \$250,000; a \$100 special assessment; and three years' supervised release.
Conspiracy to Commit Money Laundering	18 U.S.C. § 1956(h)	20 years' imprisonment; a fine of \$500,000 or twice the laundered money, whichever is greater; three years' supervised release; and a \$100 special assessment.

II. Relative Culpability of Conspirators

Four SB Medical employees have already been sentenced by this Court, and an additional defendant, Shlomo Rabi, awaits sentencing on October 2, 2015. The chart below shows each defendant's sentence, if applicable, as well as his or her Guidelines range, salary, and role in the conspiracy. The defendants are listed in the order of their culpability as determined by the Government, with Burke being listed as the most culpable defendant convicted in this case.

#	Defendant	Sentence	Guidelines	Salary	Role
1	David Burke	TBD	108-135 months	\$1,301,626	Director of sales and leader of day-to-day operations. Trained sales team in misleading clients. Instructed drop-shippers to use false names and mishandle cold-chain products and advised foreign suppliers on how to subvert U.S. customs.
2	Shlomo Rabi	TBD	51-60 months	\$356,901	Senior member of sales team. Recruited, trained, and supervised co-conspirators such as Ibrahimian, Mirlis, and R. Rabi.
3	David Stein	8 Months Imprisonment	63-78 months	\$174,015	Operated primary warehouse in Baltimore, Md. Stored and shipped over \$13 million in misbranded drugs.
4	Ibrahimian/Mirlis	Probation	12-15 months	\$173,469 (combined)	Members of SB Medical Sales staff. Engaged in deceptive practices under the direction of Burke and Sholmo Rabi.
6	Rivka Rabi	Probation	15-19 months	\$54,821	Operated secondary warehouse in New Jersey. Stored and shipped over \$4 million in misbranded drugs.

III. Sentencing Guidelines Calculation

The defendant's Guidelines Range was properly calculated by the Probation Office as **108-135 months' imprisonment**, given a total offense level of 31 and a criminal history category of I:

Guideline	
Base Offense Level (Section 2B1.1(a)(2))	6
Loss more than \$7,000,000.00 and less than \$20,000,000 (Section 2B1.1(b)(1)(K))	+20
Offense committed outside United States/ Sophisticated Means (Section 2B1.1 (b)(10))	+2
Money Laundering Conviction under 18 U.S.C. § 1956 (Section 2S1.1(b)(2)(B))	+2
Leadership role (Section 3B1.1(a))	+4
Timely acceptance of responsibility (Section 3E1.1(a) and (b))	-3
TOTAL	31

PSR ¶¶ 51-62. Given the defendant's timely acceptance of responsibility, the Government will move the Court for a one-level reduction under U.S.S.G. § 3E1.1(b), which the Probation Office has appropriately included in its calculations.

IV. Application of Sentencing Factors

Although the Sentencing Guidelines are advisory, the Court is required to “consult those Guidelines and take them into account when sentencing.” *United States v. Booker*, 543 U.S. 220, 264 (2005). A “district court shall first calculate ... the range prescribed by the guidelines. Then, the court shall consider that range as well as other relevant factors set forth in the guidelines and those factors set forth in [18 U.S.C.] § 3553(a) before imposing the sentence.” *United States v. Hughes*, 401 F.3d 540, 546 (4th Cir. 2005) (citation omitted). The § 3553(a) factors include:

- the nature and circumstances of the offense and the history and characteristics of the defendant;
- the need for the sentence imposed to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; to afford adequate deterrence to criminal conduct; to protect the public from further crimes of the defendant; and to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner;
- the kinds of sentences available;
- the kinds of sentence and the sentencing range established for the applicable category of offense committed by the applicable category of defendant as set forth in the guidelines;
- any pertinent policy statement;
- the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and

Here, three of these factors are particularly relevant: (1) the nature and circumstances of the offense; (2) the need for the sentence imposed to reflect the seriousness of the offense and afford adequate deterrence to criminal conduct; and (3) the need to avoid unwarranted sentence disparities among defendants who have been found guilty of similar conduct.

A. Nature and Circumstances of the Offense

Mr. Burke's actions created grave risks to public safety. The drugs and devices he sold are dangerous if not handled, administered, and used correctly. That is why the drugs and devices are highly regulated by the FDA. The FDA must approve any prescription drug or device before it can be sold in the United States. Even when a prescription drug or device is approved, the FDA requires that it contain very specific labels, warnings, and instructions in order to educate doctors about how to administer the drug or device safely and to warn patients about possible side effects. *See* 21 U.S.C. § 355(d) (mandating that the FDA approve new drug applications only if the drug is "safe for use under the conditions prescribed, recommended, or suggested ***in the proposed labeling***") (emphasis added). Drug labeling thus serves as "[t]he centerpiece of [the FDA's] risk management" strategy because it "communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." 71 Fed. Reg. 3934 (2006).

The drugs and devices Burke sold did not contain FDA-required labels, and therefore posed serious safety risks. *See* FDA Letter to Doctors about Risks of

Purchasing Unapproved Versions of Botox and Other Medications from Foreign or Unlicensed Suppliers, <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm> (“Medications that are not approved by FDA may lack necessary and required labeling to assure their appropriate and safe use.”). Many were missing FDA-mandated “Black-Box Warnings,” which are required “in the labeling for medications that have special problems, particularly ones that may lead to death or serious injury.” *Id.* Many were also missing FDA-mandated “Medication Guides,” which provide information to “help patients avoid serious adverse events.” *Id.* Burke was well-aware of this risk, since he himself forwarded a letter from the FDA to a co-conspirator, stating the FDA is “very concerned” that unapproved foreign drugs and devices “may cause harm to patients, because they may be unsafe or ineffective.” PSR ¶ 31(h).

These public health risks were compounded by the reckless procedures Burke implemented to cut costs and avoid detection by law enforcement. These include shipping cold-chain products through circuitous routes and without dry ice to avoid detection, storing products in messy private residences, and maintaining little oversight of SB Medical’s convoluted supply-chain. Such illicit distribution networks pose “a number of potential risks” to patients, including the risk of receiving drugs that may be “expired, subpotent, contaminated or counterfeit.” *See* Senate Committee on Health, Education, Labor and Pensions, Testimony of John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA (May 20, 2004) (“*Taylor Testimony*”), <http://www.fda.gov/NewsEvents/Testimony/ucm113825.htm>.

These risks were surely present in this case given Burke's cavalier attitude towards the shipping and storage.

Because of Burke's actions, thousands of patients were injected with misbranded and mishandled drugs and devices without their knowledge or consent. As the FDA has warned, "[w]hen consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause." *Taylor Testimony*. These risks appear to have come to fruition in this case, as at least one medical professional complained that their products caused side effects in five of ten patients, necessitating emergency room visits. *See* TC Medical PSR ¶ 32. And the government may never know whether patients had their illnesses prolonged, or even whether patients died, because they did not receive the full strength of the drugs or devices that Burke sold.

B. The Need for the Sentence To Reflect the Seriousness of the Offense, Promote Respect for the Law and Afford Adequate Deterrence

The smuggling of misbranded pharmaceuticals into this country has boomed because the leaders of that illegal business have made a calculated choice that the rewards greatly outweigh the risk. Burke is a perfect example: he personally earned over \$1.3 million in salary and commissions and explicitly made the determination that this kind of money, and the lifestyle it provided, was worth

whatever prison sentence he might someday face. *See* PSR ¶ 31(e) (Burke: “you should make as much as you can while you can ... I go through with the thought of every day is my last and make the best of it”).

The money to be made from flouting FDA regulations is not going to decrease, nor will the resources that it takes to investigate and prosecute sophisticated smuggling networks like the one Burke operated. The only way to change the cost-benefit analysis for this crime is to impose meaningful penalties on those who are convicted. If this Court does so, there is every reason to believe that would-be smugglers will get the message. *See United States v. Martin*, 455 F.3d 1227, 1240 (11th Cir. 2006) (“Because economic and fraud-based crime are more rational, cool, and calculated than sudden crimes of passion or opportunity, these crimes are prime candidates for general deterrence.”).

C. The Need for Avoid Unwarranted Sentencing Disparities

The Court sentenced David Stein to 8 months’ imprisonment, noting that the this below-guidelines sentence was warranted because Mr. Stein did not play a leadership role in the conspiracy and personally received only a fraction of SB Medical’s massive proceeds. These very same factors cut in favor of a far stricter sentence for Mr. Burke. Burke received over **seven times** as much money as Stein, and over three times as much as defendants Stein, Ibrahimian, Mirlis, and Rivka Rabi **combined**. This disparity in compensation reflects Burke’s leadership role in the company. In Burke’s own words, he was the “MOST instrumental part of this company.” PSR ¶ 31(s).

Burke's position vis-à-vis Stein is best illustrated by instant messages in which Burke provided constant and detailed instructions to Stein, mixed with verbal abuse. In one chat, for instance, Burke was furious that Stein had not sent a shipment, exclaiming "Dave!!! F- -k!!! They didn't pick up. ... I just called and arranged it ... honestly I don't know what you do for us ... service is seriously lacking." On a separate occasion, Burke told Stein: "Wow man ... Pulling teeth to get expected info from you." On still another occasion: "U said 'OK' did you not? Now its not OK? ... This is retarded ... simple task bro." To achieve sentencing consistency, the Government believes that Burke's sentence should reflect the fact that he oversaw all aspects of the company, earned seven times Stein's salary, and acted as Stein's boss.

Conclusion

The smuggling and distribution of misbranded pharmaceuticals conducted by unlicensed and unscrupulous entities like SB and TC Medical is a serious and widespread problem. Because these crimes are calculated and pre-meditated, their investigation and prosecution is resource-intensive and difficult. Thankfully, the same sophistication that makes these criminals hard to catch, also makes them easy to deter. A meaningful sentence for David Burke will send a message that is likely to be heard by smugglers around the world who would otherwise be willing to endanger untold numbers of American patients and risk extradition and prosecution for the chance to make the lavish profits that Burke made.

Respectfully submitted,

Dana J. Boente
United States Attorney

By: /s/
Kellen S. Dwyer
Jay V. Prabhu
Assistant United States Attorneys
United States Attorney's Office
Eastern District of Virginia
2100 Jamieson Avenue
Alexandria, Virginia 22314
Ph: (703) 299-3700
Fax: (703) 299-3981
Email: kellen.dwyer@usdoj.gov

Date: September 9, 2015

Certificate of Service

I hereby certify that on September 9, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of filing (NEF) to counsel of record for the defense.

I also certify that on September 9, 2015, I will send a true and correct copy of the foregoing by e-mail to the following:

Kelly M. Smihal
United States Probation Officer
Alexandria, VA
703/299-2304
Kelly_Smihal@vaep.uscourts.gov

By: /s/
Kellen S. Dwyer
Assistant United States Attorney
United States Attorney's Office
Eastern District of Virginia
2100 Jamieson Avenue
Alexandria, Virginia 22314
(703) 299-3707 office, (703) 299-3981 fax
kellen.dwyer@usdoj.gov